REMARKS

Claims 1-7, 11 and 14 presently appear in this case. No claims have been allowed. The official action of July 3, 2003, has now been carefully studied. Reconsideration and allowance are hereby respectfully urged.

Briefly, the present invention relates to DNA encoding the human MORT-1 protein and fragments and analogs thereof, as well as vectors, transformed host cells and methods of producing same. The invention also relates to a recombinant animal virus vector which includes such a sequence, as well as a virus surface protein capable of binding a specific target cell surface receptor.

The examiner states that, although the PTO-1449 submitted on April 3, 2001, is in the file, the rest of the IDS is missing. The examiner's attention is invited to the second paragraph on page 3 of applicant's transmittal letter of April 3, 2001, transmitting the filing of the present application. This paragraph reads:

> Certain documents were previously cited or submitted to the Patent and Trademark Office in the following prior application, 08/860,082, which is relied upon under 35 U.S.C. §120. Applicants identify these documents by attaching hereto a form PTO-1449 listing these documents, and request that they be considered and made of record in accordance with 37 C.F.R. §1.98(d). Per §1.98(d), copies of these documents need not be filed in this application.

Accordingly, it is requested that the documents cited on the PTO-1449, which the examiner concedes is of record, be officially considered in this case and that the initialed copy of the form PTO-1449 be returned to applicant in accordance with usual procedure.

The examiner has acknowledged receipt of applicant's three Israeli priority applications. The examiner states that applicant is entitled to a priority date of February 19, 1995.

As there are no intervening references between the December 15, 1994, priority date and the February 19, 1995, priority date, applicant will not traverse the examiner's holding as to the effective filing date at the present time. This is without prejudice toward explaining why applicant is entitled to the priority date of December 15, 1994, when and if this becomes necessary in order to overcome prior art.

Claims 1-7 and 11 have been rejected under 35 U.S.C. §101 as being directed to non-statutory subject matter. The examiner suggests reciting an isolated DNA molecule to overcome this rejection.

The claims have now been amended to insert the word "isolated", thus obviating this rejection.

Claims 1-7 and 11 have been rejected under 35 U.S.C. §112, first paragraph, written description, specifically with respect to the second paragraph of claim 1. The examiner

states that this is not a utility rejection. The examiner further states that binding to the FAS ligand receptor is only a physical property and not a function of the MORT-1 protein encoded by the claimed polynucleotide. Further, the examiner states that claim 1(2) does not specify that the analog binds to FAS-IC. This rejection is respectfully traversed.

First of all, claim 1 has been amended to specify in paragraph 2 that it is the analog that binds with the FAS-IC. With respect to the examiner's comment that binding to FAS-IC is "only a physical property and not a function of the MORT-1," the relevance of this comment with respect to the written description of 35 U.S.C. §112 is not fully understood. The ability of a protein to bind to another protein is both a physical property and a function. Binding in and of itself is evidence of a function. Nevertheless, the examiner's attention is invited to the Guidelines for Examination of Patent Applications under the 35 U.S.C. §112, ¶1, "Written Description" Requirement as published at 66 Federal Register 1099, 1106 (January 5, 2001), where it states:

> An applicant may also show that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics which provide evidence that applicant was in possession of the claimed invention, *i.e.*, complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed

correlation between function and structure, or some combination of such characteristics.

Here, the analog of claim 1(2) is defined by a complete or partial structure and other physical and/or chemical properties. The examiner concedes that the binding is a physical property. There is a partial structure because the DNA encoding it must be capable of hybridizing to the cDNA encoding SEQ ID NO:2 under moderately stringent conditions. Thus, this combination of partial structure and physical and/or chemical properties is sufficient to show that applicant was in possession of the claimed invention. Binding alone is sufficient to establish the function of serving in affinity chromatography to isolate MORT-1 protein.

The examiner's reference to cell death is queried as there is no mention of cell death in claim 1. The function of the protein or polypeptide encoded by the DNA of claim 1 may be any function disclosed in the specification. Note that the affinity chromatography function is mentioned, for example, at page 21, lines 5-9, where it states that affinity chromatography may be used to characterize additional proteins, factors, receptors, etc., which are capable of binding to the MORT-1 protein of the invention. This, of course, includes FAS-IC, as is stated in the following two lines. Accordingly, the present claims fully satisfy the written description guidelines, as it is perfectly acceptable

to show that one is in possession of a compound by identifying characteristics which include physical properties. Reconsideration and withdrawal of this rejection is therefore respectfully urged.

Claims 1-7 and 11 have been rejected under 35 U.S.C. §112, first paragraph, because the specification, while being enabling for a cDNA sequence encoding the MORT-1 protein of SEQ ID NO:2, does not reasonably provide enablement for sequences encoding an analog of that protein. The examiner states that the claims encompass a "genomic DNA" sequence and there is no disclosure of such a genomic sequence. This part of the rejection is respectfully traversed.

The examiner's attention is drawn to the present specification at page 12, lines 1-7, where it states that proteins capable of binding to FAS-IC having at least partial homology to the sequence of the present invention can be found using either a CDNA library or a genomic DNA library. Thus, while the specific example used to find the protein of the present invention used a cDNA library, those of ordinary skill in the art would understand that the same experiment could have been done by screening a genomic DNA library, and that would have isolated the genomic DNA. Accordingly, the present invention does teach how to find the genomic DNA sequence, and this can be identified without undue experimentation.

Furthermore, new claim 14 has now been added, which specifies that the entire DNA is a coding region. This effectively excludes genomic DNA, but includes not only cDNA, but also synthetic DNA which encodes an analog or a fragment. Accordingly, at least new claim 14 should be considered to be free of this rejection. Reconsideration and withdrawal of this part of the rejection is therefore respectfully urged.

The examiner states with respect to claims 6 and 7, that the specification, while being enabling for "isolated" transformed host cells, does not reasonably provide enablement for any transformed host cells. The examiner states that the claims encompass gene therapy.

Claims 6 and 7 have now been amended to specify that the cells are "isolated", thus excluding gene therapy from the scope thereof. Reconsideration and withdrawal of this rejection is therefore respectfully urged.

The examiner states that, while claims 1-7 and 11 are enabling for a cDNA sequence of SEQ ID NO:1, the specification does not reasonably provide enablement for an analog of a DNA sequence encoding the amino acid sequence of SEQ ID NO:2, which binds to the intracellular domain of the FAS ligand receptor and is capable of hybridization to the cDNA encoding SEQ ID NO:2 under moderately stringent conditions. The examiner states that the claims encompass

unrelated sequences with unknown function encoding a polypeptide that shares with SEQ ID NO:2 a fragment that binds to FAS-IC. The examiner states that these types of modified DNAs have not been enabled. The examiner also states that the claims encompass polynucleotides comprising non-disclosed nucleic acid sequences attached to polynucleotides that encode MORT-1 protein. The examiner states that when given the broadest reasonable interpretation, it would be expected that a substantial number of the hybridizing molecules encompassed by the claims would not share either structural or functional properties that encode MORT-1 protein. This part of the rejection is respectfully traversed.

As to the examiner's statement that the claims encompass unrelated sequences with unknown function encoding a polypeptide that shares with SEQ ID NO:2 a fragment that binds to FAS-IC, this is an incorrect reading of claim 1. Claim 1(3) reads:

> An isolated DNA molecule comprising ... a DNA coding sequence consisting of a DNA sequence which encodes a fragment of said MORT-1 protein which binds with FAS-IC.

Thus, while the DNA molecule may include other portions, the coding sequence consists of a fragment of SEQ ID NO:2 which binds with FAS-IC. Thus, the claim does not read on a polypeptide that shares with SEQ ID NO:2 a fragment that binds to FAS-IC. The DNA must encode only the fragment, and not

other polypeptides that include such a fragment, in view of the "consisting of" language used with respect to the DNA coding sequence.

Furthermore, the examiner's interpretation of claim 1(2) is also incorrect where the examiner states that a substantial number of the hybridizing molecules encompassed by the claims would not share either structural or functional properties with polynucleotides that encode MORT-1 protein. The DNA sequence of claim 1(2) must encode an analog, which analog binds with the FAS-IC, and it is that sequence which must be capable of hybridizing to the cDNA encoding SEQ ID NO:2 under moderately stringent conditions. Thus, it is not some other part of the DNA molecule that may hybridize to the cDNA encoding SEQ ID NO:2, but it must be that sequence which encodes the analog that binds with the FAS-IC. If that sequence both binds to FAS-IC and hybridizes to the cDNA encoding SEQ ID NO:2 under moderately stringent conditions, then it would be expected to share substantial sequence identity with SEQ ID NO:2. As explained in applicant's previous amendment, of February 24, 2003, it would be expected to require at least 75% homology. Any such sequence thus shares structural and functional (or physical) properties with polynucleotides that encode MORT-1 protein. Reconsideration

and withdrawal of this part of the rejection is therefore also respectfully urged.

It is submitted that all of the claims now present in the case clearly define over the references of record and fully comply with 35 U.S.C. §112. Reconsideration and allowance are therefore earnestly solicited.

Respectfully submitted,

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